

International preliminary examination report

International Application No.

PCT/RU 2003/000346

V. Statement in accordance with article 35 (2) with regard to novelty, to inventive step and to industrial application; endnote proving such statements.

1. Statement

Criterion of novelty (N)	Claims: 2-3, 6-9	Yes
	Claims: 1, 4-5, 10-42	No
Inventive step (IS)	Claims: 2-3, 6-9	Yes
	Claims: _____	No
Industrial application (IA)	Claims: 1-42	Yes
	Claims: _____	No

2. Citation of document (Rule 70.7)

D1- RU 2169139 C1 (Closed Joint-Stock Company "Center of Modern Medicine "Medicor"), 20.06.2001.

D2- RU 2163122 C1 (Abidov M.T.), 20.02.2002;

D3- EP 0617024 A (LIMAD MARKETING EXP & IMP), 28.09.1994 (new document).

D4- EP 0612733 A (LIMAD MARKETING EXP & IMP), 31.08.1994 (new document).

D5- RU 2167659 C1 (Closed Joint-Stock Company "Center of Modern Medicine "Medicor" etc.), 27.05.2001 (new document).

In document D1 alkali salt production or alkaline-earth salts 5- amino-2,3-dihydro-1,4-phthalazinedione has been presented; such salt is used as immunocorrective, anti-inflammatory and anti-toxic drugs.

Compounds described in D1, (see claims 1-2, examples 1-2) are included in claims 1, 4, 5, 10-42, when A, B, Z = -CH-; R=Li, Na, K; R¹=NH₂.

Compounds under claims 2, 3, 6-9 are different from the known compounds due to the other substituents A, B, Z, R, and R¹.

Document D2 describes drug containing sodium salt 5- amino-2,3-dihydro-1,4-phthalazinedione such as immunomodulator, anti-inflammatory and anti-toxic drugs.

Compounds described in D2 (see page 3, 5 paragraph, formula, abstract) are included in claims 1, 4, 5, 10-42, of the present application, when A, B, Z = -CH-; R= Na; R¹=NH₂.

Compounds under claims 2, 3, 6-9 are different from known compounds due to other substituents A, B, Z, R, and R¹.

Documents D3-D4 disclose the use of 5-aminophthaloylhydrazide or its salts as anti-inflammatory agent, as anti-oxidant and antitoxic agent. Known from patent sources D3-D4 compounds (see formula, abstract) are included in claims 1, 4, 5, 10-42, when A, B, Z = -CH-; R= Na; R¹=NH₂.

Compounds under claims 2, 3, 6-9 are different from known compounds due to other substituents A, B, Z, R, and R¹.

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Additional column

Document D5 describes amino derivatives 2,3-dihydro-1,4-phthalazinedione and its salts as immunocorrective means.

Compounds described in D5 (see formula, abstract) are included in claims 1, 4, 5, 10-42, of the present application, when A, B, Z = -CH₂-; R=Li, Na, K; R¹= NH₂.

Compounds under claims 2, 3, 6-9 are different from known compounds due to other substituents A, B, Z, R, and R¹.

Criterion of novelty

Claims 1, 4, 5, 10-18 do not comply with the Criterion of Novelty as they contain the known compounds.

As the compounds under claim 1 do not comply with the Criterion of Novelty, pharmaceutical composition (claims 19-42) containing these compounds also does not comply with the Criterion of novelty.

Inventive step

The summary of this invention is created the medicine with significant normalizing effect to intracellular processes, in particular resolving metabolic acidosis and fixing free radicals. Use cyclic bioisosters of purine system, applied in claims 2, 3, 6-9, for solving the task is not evident for specialists in this field of technique, as it is not evident from the prior art of technique, that the compounds applied for in these claims may possess the said potency.

Therefore the compounds under claims 2, 3, 6-9 may be acknowledged as effective and in compliance with Inventive Step criterion.

As for the new compounds pertaining to benzo [d]-3H-pyridazine-1,4-diones, for their acknowledgement and in order to bring them in compliance with the Inventive Step criterion, the Applicant should demonstrate their extraordinary features in comparison with close-in analogues presented in D1-D5, as antioxidant features and normalizing effect to the mental processes of such analogues are known, e.g. from D2 (page 3, paragraph 5).

Industrial application

Claims 1-42 are in compliance with the Industrial application criterion.

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